



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,257	08/20/2004	Richard J Budhu	21044P	3816

210 7590 11/28/2006

MERCK AND CO., INC  
P O BOX 2000  
RAHWAY, NJ 07065-0907

EXAMINER

CHU, YONG LIANG

ART UNIT PAPER NUMBER

1626

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/505,257	<b>Applicant(s)</b> BUDHU ET AL.	
	<b>Examiner</b> Yong Chu	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17, 19, and 28-29 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Claims 1-17, 19, and 28-29 are currently pending in the instant application.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 80-94 are drawn to more than one inventive concept (as defined in PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

Page 3

- Page 3

Page 3

Page 3



Page 3

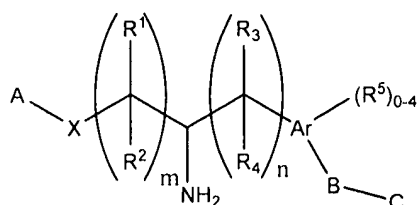
Page 3



Art Unit: 1626

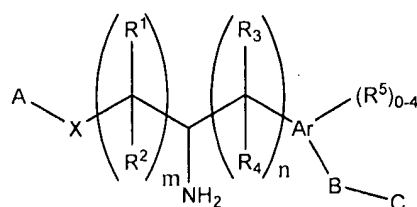
$-\text{CO}_2\text{H}$ ,  $-\text{PO}_3\text{H}_2$ ,  $-\text{PO}_2\text{H}_2$ ,  $-\text{SO}_3\text{H}$ , and  $-\text{PO}(\text{R}^8)\text{OH}$ , wherein  $\text{R}^8$  is defined in claim 1; **Ar** is phenyl; when **C** is phenyl and Het then **B** is selected from the group consisting of:  $\text{C}_{1-6}$ alkyl, ..., and  $-(\text{CHOH})-$ , as depicted in claim 1;

Group III: Claims 1-15, and 29 are drawn to products of formula (I)



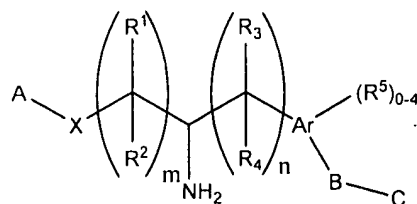
, wherein **A** is selected from the group consisting of  $-\text{CO}_2\text{H}$ ,  $-\text{PO}_3\text{H}_2$ ,  $-\text{PO}_2\text{H}_2$ ,  $-\text{SO}_3\text{H}$ , and  $-\text{PO}(\text{R}^8)\text{OH}$ , wherein  $\text{R}^8$  is defined in claim 1; **Ar** is phenyl; when **C** is phenyl or Het, then **B** is phenyl or Het, as depicted in claim 1;

Group IV: Claims 1-15, and 29 are drawn to products of formula (I)



, wherein **A** is selected from the group consisting of  $-\text{CO}_2\text{H}$ ,  $-\text{PO}_3\text{H}_2$ ,  $-\text{PO}_2\text{H}_2$ ,  $-\text{SO}_3\text{H}$ , and  $-\text{PO}(\text{R}^8)\text{OH}$ , wherein  $\text{R}^8$  is defined in claim 1; **Ar** is phenyl; when **C** is  $\text{C}_{1-8}$ alkyl, ... or  $-\text{CHOH}-\text{C}_{1-6}$ alkyl, then **B** is phenyl or Het, as depicted in claim 1;

Group V: Claims 1-15, and 29 are drawn to products of formula (I)

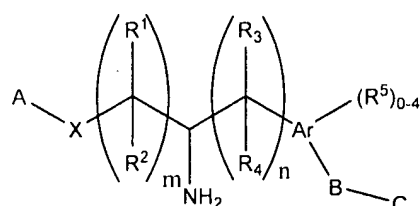


, wherein **A** is selected from the group consisting of  $-\text{CO}_2\text{H}$ ,  $-\text{PO}_3\text{H}_2$ ,  $-\text{PO}_2\text{H}_2$ ,  $-\text{SO}_3\text{H}$ , and  $-\text{PO}(\text{R}^8)\text{OH}$ , wherein  $\text{R}^8$  is defined in claim 1; **Ar** is

Art Unit: 1626

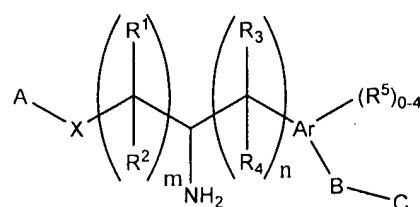
naphthyl; when **C** is not present then **B** is selected from the group consisting of: phenyl, C<sub>5-16</sub>alkyl, ..., and -N(R<sup>6</sup>)(R<sup>7</sup>)-(C=O)- C<sub>3-14</sub>alkynyl, as depicted in claim 1;

Group VI: Claims 1-15, and 29 are drawn to products of formula (I)



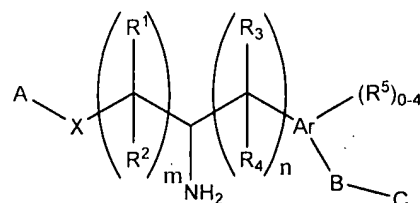
, wherein **A** is selected from the group consisting of -CO<sub>2</sub>H, -PO<sub>3</sub>H<sub>2</sub>, -PO<sub>2</sub>H<sub>2</sub>, -SO<sub>3</sub>H, and -PO(R<sup>8</sup>)OH, wherein R<sup>8</sup> is defined in claim 1; **Ar** is naphthyl; when **C** is phenyl and Het then **B** is selected from the group consisting of: C<sub>1-6</sub>alkyl, ..., and -(CHOH)-, as depicted in claim 1;

Group VII: Claims 1-15, and 29 are drawn to products of formula (I)




, wherein **A** is selected from the group consisting of -CO<sub>2</sub>H, -PO<sub>3</sub>H<sub>2</sub>, -PO<sub>2</sub>H<sub>2</sub>, -SO<sub>3</sub>H, and -PO(R<sup>8</sup>)OH, wherein R<sup>8</sup> is defined in claim 1; **Ar** is naphthyl; when **C** is phenyl or Het, then **B** is phenyl or Het, as depicted in claim 1;

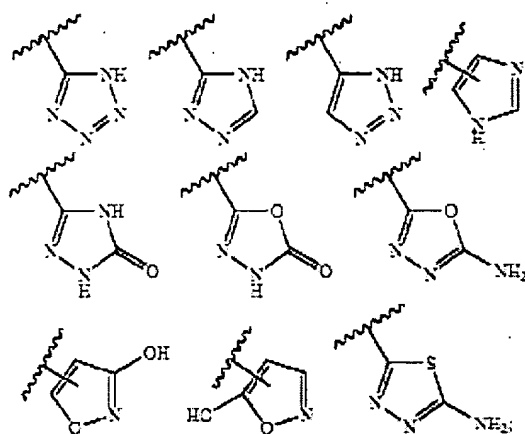
Group VIII: Claims 1-15, and 29 are drawn to products of formula (I)



, wherein **A** is selected from the group consisting of -CO<sub>2</sub>H, -PO<sub>3</sub>H<sub>2</sub>, -PO<sub>2</sub>H<sub>2</sub>, -SO<sub>3</sub>H, and -PO(R<sup>8</sup>)OH, wherein R<sup>8</sup> is defined in claim 1; **Ar** is



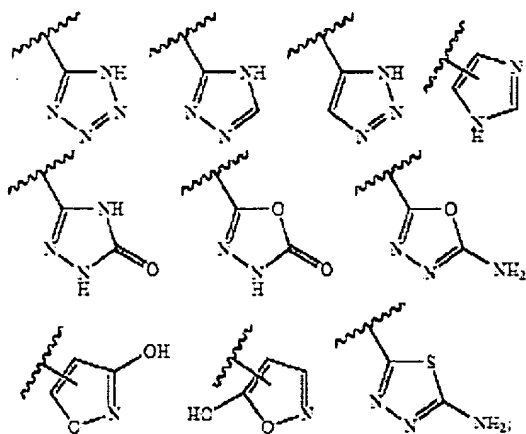
$$\text{A}-\text{X}-\text{C}(\text{R}^1)(\text{R}^2)-\text{C}(\text{NH}_2)(\text{R}^3)(\text{R}^4)-\text{Ar}-\text{B}-\text{C}(\text{R}^5)_{0-4}$$
 , wherein **A** is selected from the group consisting of



**B** is selected from the group consisting of: phenyl, C<sub>5-16</sub>alkyl, ..., and -N(R<sup>6</sup>)(R<sup>7</sup>)-(C=O)-C<sub>3-14</sub>alkynyl, as depicted in claim 1;

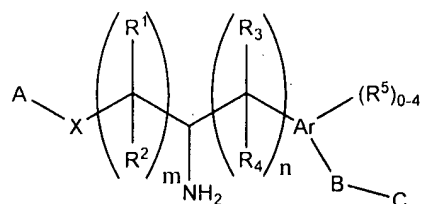
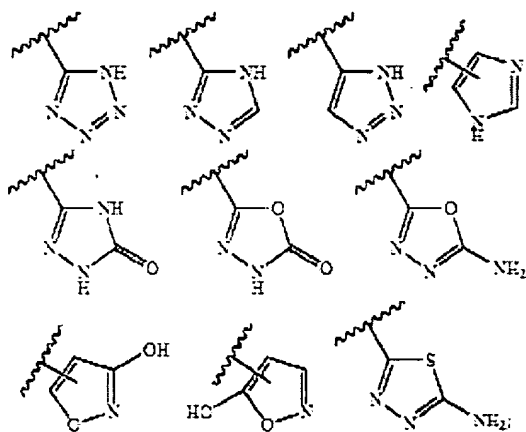
$$\begin{array}{c}
 \text{R}^1 \\
 | \\
 \text{A}-\text{X}-\text{C}_1-\text{C}_2-\text{C}_3-\text{Ar} \\
 | \quad | \quad | \quad | \\
 \text{R}^2 \quad \text{NH}_2 \quad \text{R}_4 \quad \text{R}^3 \\
 \text{m} \quad \quad \quad \text{n}
 \end{array}
 \quad \text{B}-\text{C} \quad \text{(R}^5\text{)}_{0-4}$$
 , wherein **A** is selected from the group consisting of

Art Unit: 1626

; **Ar** is phenyl; when **C** is phenyl and Het

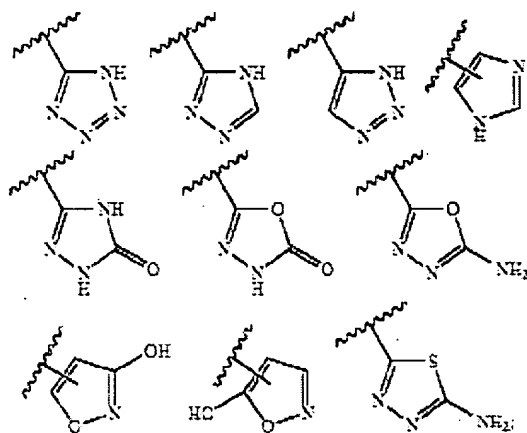
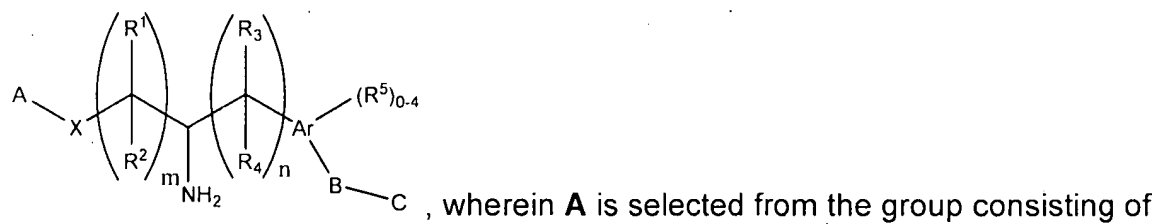
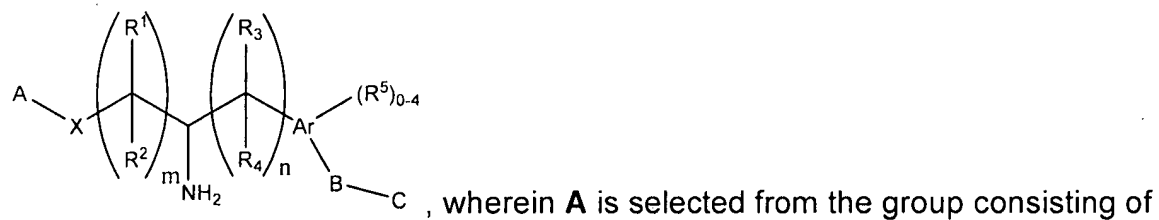
then **B** is selected from the group consisting of: C<sub>1-6</sub>alkyl, ..., and -(CHOH)-, as depicted in claim 1;

Group XI: Claims 1-15, and 29 are drawn to products of formula (I)

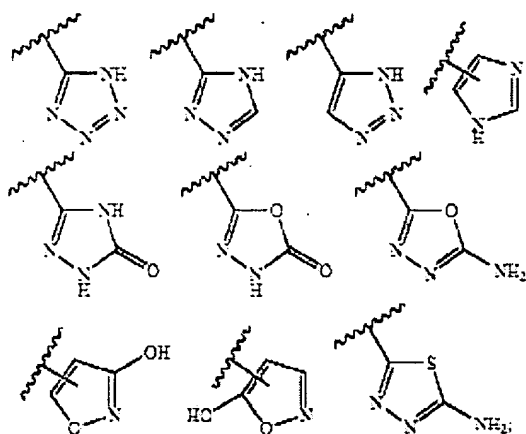
, wherein **A** is selected from the group consisting of; **Ar** is phenyl; when **C** is phenyl or Het,

then **B** is phenyl or Het, as depicted in claim 1;

Art Unit: 1626

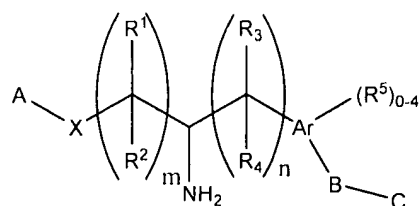
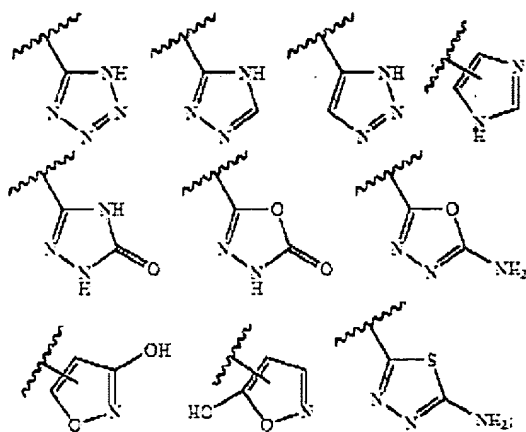
Group XII: Claims 1-15, and 29 are drawn to products of formula (I); **Ar** is phenyl; when **C** is C<sub>1-8</sub>alkyl, ... or –CHOH-C<sub>1-6</sub>alkyl, then **B** is phenyl or Het, as depicted in claim 1;Group XIII: Claims 1-15, and 29 are drawn to products of formula (I)

Art Unit: 1626

; **Ar** is naphthyl; when **C** is not present

then **B** is selected from the group consisting of: phenyl, C<sub>5-16</sub>alkyl, ..., and -N(R<sup>6</sup>)(R<sup>7</sup>)-  
(C=O)- C<sub>3-14</sub>alkynyl, as depicted in claim 1;

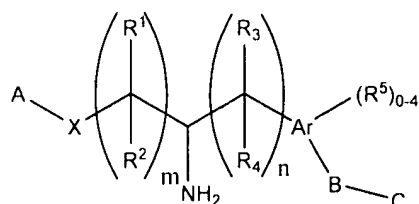
Group XIV: Claims 1-15, and 29 are drawn to products of formula (I)

, wherein **A** is selected from the group consisting of; **Ar** is naphthyl; when **C** is phenyl and Het

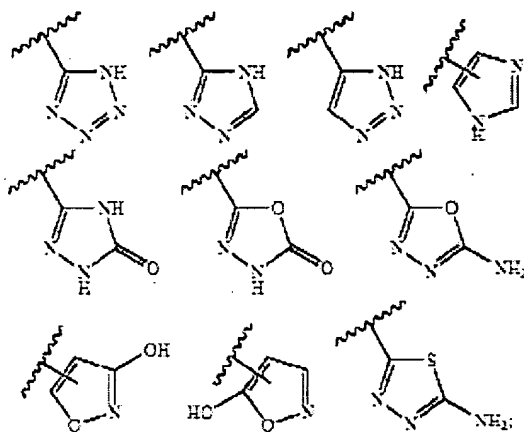
Art Unit: 1626

then **B** is selected from the group consisting of: C<sub>1-6</sub>alkyl, ..., and -(CHOH)-, as depicted in claim 1;

Group XV: Claims 1-15, and 29 are drawn to products of formula (I)



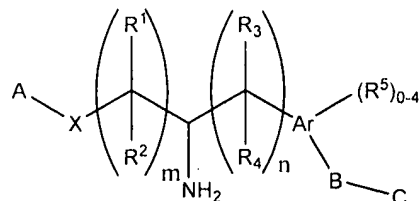
, wherein **A** is selected from the group consisting of



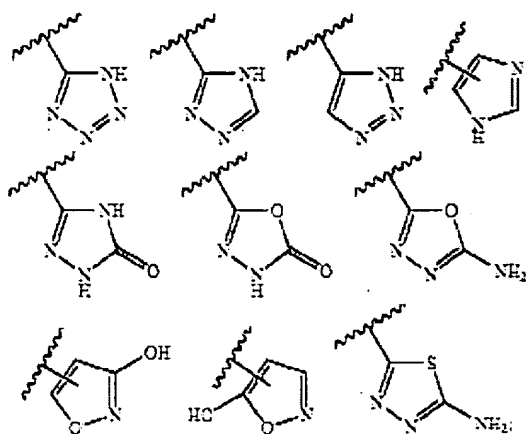
; **Ar** is naphthyl; when **C** is phenyl or Het,

then **B** is phenyl or Het, as depicted in claim 1;

Group XVI: Claims 1-15, and 29 are drawn to products of formula (I)



, wherein **A** is selected from the group consisting of



; **Ar** is naphthyl; when **C** is  $C_{1-8}$ alkyl,...or –

CHOH- $C_{1-6}$ alkyl, then **B** is phenyl or Het, as depicted in claim 1;

Group XVII: Claims 16,17, and 19 are drawn to a method of treating an immunoregulatory abnormality in a mammalian patient comprising administering to said patient a compound, according to claim 1.

Group XVIII: Claim 28 is drawn to a method of suppressing the immune system in a mammalian patient in need of immunosuppression comprising administering to said patient a compound, according to claim 1

Due to the numerous and widely divergent variables in the compound of formula (I), it would be impossible to list all groups under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention at comparable scope as stated supra (a product or a method of use of said product) by identifying another specific embodiment, i.e. another value for m,n, R1-R4, X, B, C, A, not listed in the exemplary groups of the invention and examiner will endeavor to group the same.

Art Unit: 1626

Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Additionally, the vastness of the claimed subject matter, and the complications in understanding the claimed subject matter imposes a serious burden on any examination of the claimed subject matter.

Furthermore, with respect to **Groups I-XVIII**, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specially designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Moreover, according to 37 CFR 1.475(c),

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than one product, process, and method of use. According to 37 CFR 1.475(e),

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

**As a result, the claims lack unity of invention and applicant is required to elect a single invention.**

The claims directed to a single method of preparation and a single method of use will be examined along with the elected invention so long as it is commensurate in scope therewith.

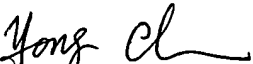
***Telephone Inquiry***

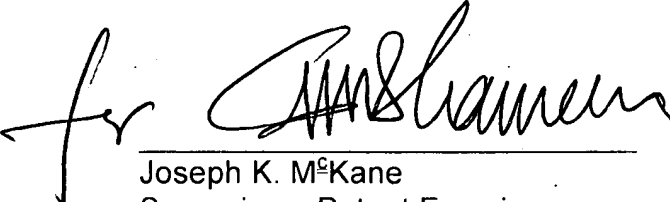
Any inquiry concerning this communication or earlier communications from the examiner should be directed Yong Chu whose telephone number 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1626

  
\_\_\_\_\_  
Yong Chu, Ph.D.  
Patent Examiner, AU 1626

  
\_\_\_\_\_  
Joseph K. McKane  
Supervisory Patent Examiner  
AU 1626